Patent
Attorney Docket No. 101.0042-05000
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Gary Karlin Michelson, M.D.	)	
	)	
Serial No. (Cont. of 09/563,705)	)	(Group Art Unit: 3731)
	)	
Filed: March 15, 2002	)	(Examiner: U. Ho)
	)	
For: SPINAL IMPLANT CONTAINING BONE MORPHOGENETIC PROTEIN (as amended)	)	

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

AMENDMENT

Prior to examination of this application, the following amendments and remarks are submitted:

IN THE TITLE:

Please rewrite the title (with the changes as shown in the attachment) to read as follows:

--SPINAL IMPLANT CONTAINING BONE MORPHOGENETIC PROTEIN--.

IN THE SPECIFICATION:

Please amend the specification (with the changes as shown in the attachment) to read as follows:

Paragraph bridging pages 19 and 20:

--Referring to Figure 18, a drilling template instrument 50 for creating a pair of insertion holes 53a and 53b in each of the vertebrae V for receiving each of the projection 16 and 17 respectively is shown. The drilling template instrument 50 has a template 52 with a central aperture 54 therethrough and guide passages 55 and 56 for guiding a drill bit 51 of a drilling tool. Attached to the template 52 is a handle 58 which angles away from the template 52 so as not to obstruct the line of sight of the surgeon and to allow easy access to the template 52 and easy access to the guide holes 55 and 56 for the drill bit 51. Extending from the center of the bottom surface of the template 52 is a central member 59 (similar in structure and function to the central bar 35) for mating to an already implanted intervertebral spinal fusion implant 40. The central member 59 interdigitates with the depression 42 of the spinal fusion implant 40 so that the template 52 is properly oriented about the spinal fusion implant 409 and the guide holes 55 and 56 are properly oriented with respect to the vertebrae V adjacent to the spinal fusion implant 40. The alignment rod 70 serves as a guide post for the drill template instrument 50 as it fits through the central aperture 54 of the template 52 and aligns the template 52 with respect to the spinal; fusion implant 40 and insures that it is coaxial. The central aperture 54 of the drilling template instrument 50 is smooth so that if it is placed over a splined alignment rod 70' the drilling template instrument 50 may be easily rotated about the splined alignment rod 70' into position such that the central member 59 is able to mate and interdigitate with the depression 44 of the spinal fusion implant 40.--

Page 21, first full paragraph:

--Referring to Figure 22, once the staple member 12 is properly placed onto the bottom flat member 84 of the driving instrument 80, the staple member 12 and the driving instrument 80 are aligned with respect to the alignment rod 70 so that the alignment rod 70 passes through the central opening 18 of the staple member 12 and is inserted into the central hollow portion 89 of the driving instrument 80. The staple member 12 and the driving instrument 80 are then lowered along the alignment rod 70 so that the sharp distal end 32 of each of the projections 16 and 17 comes into contact with the external surface of the vertebrae V and is aligned with the previously drilled insertion holes 53a and 53b.--

Page 23, second full paragraph:

--Referring to Figure 22, in the Short Method, the splined alignment rod 70' that is finely splined along its longitudinal axis is used instead of the alignment rod 70. Once the splined alignment rod 70' has been attached to the spinal fusion implant 40, the staple member 12 may be placed over the splined alignment rod 70' so that the splined alignment rod 70' passes through the aperture 18 and into the central aperture 89 of the driving instrument 80. The central aperture 89 of the driving instrument 80 is correspondingly splined to the splines of the splined alignment rod 70' so that the staple member 12 can be aligned with respect to the spinal implant 40. The alignment of the staple member 12 and the driving instrument 80 is maintained as the corresponding splines of the central aperture 89 interdigitate with the splines of the splined alignment rod 70' and prevent the rotation of the staple member 12 about the splined alignment rod 70'. The prevention of rotation about the splined alignment rod 70' is especially

important when the Short Method is used to insert the spinal fixation device 10, as no insertion holes 53a and 53b have been drilled in the vertebrae V. The staple 12 can be driven directly into the vertebrae V by the application of a high impaction force to the driving instrument 80 as described above and shown in Figure 22.--

Page 24, last paragraph:

--Referring to Figure 26, a second alternative embodiment of the spinal fixation device 210 having a staple member 212 is shown with a top member 214 that is generally rectangular5 in shape and has an upper surface 220 with openings 222a, 222b, 222c, and 222d. The top member 214 has four projections 216, 217, 218, and 219 depending from its bottom surface at each of its corners. The projections 216-217 are the same as the projections 16 and 17 described above in the preferred embodiment. The stop member 2145 has four straight sides 228a, 228b, 228c, and 228d having upper edges 225a, 225b, 225c, and 225d, respectively, that are radiused to conform to the external curvature of the vertebrae V create a smooth surface as described above for the preferred embodiment. The driving instrument 80' shown in Figure 16B is used to insert the spinal fixation device 210.--

Page 25, first paragraph:

--Referring to Figure 27, a third alternative embodiment of the spinal fixation device310 having a staple 312 with a top member 314 that is generally triangular is shown. The top member 314 has two projections 316 and 317 depending from the bottom surface of the top member 314 that engage the vertebrae V. Extending from the center of the bottom surface of the top member 314 is a central member 390 which is similar to the central bar 35 of the preferred embodiment of the spinal fixation device 10

in that the central member 390 interdigitates with the depression 44 of the spinal fusion implant 40. However, the central bar 390 also has an extension arm 392 that extends laterally from the top member 314 to span the diameter of an adjacent spinal fusion implant 41. The extension arm 392 interdigitates with the depression 44 of the spinal implant 41. The extension arm 392 has a central aperture 394 for receiving a screw 60b used to couple the extension arm 392 to the spinal fusion implant 41. In this manner, a single spinal fixation device 310 is capable of interdigitating with two adjacent spinal fusion implants 40 and 41 to clock and prevent the rotation and any excursion of the spinal fusion implants 40 and 41. The fixation of two spinal fusion implants 40and 41 is possible while leaving no protruding metal, such as the top member 314, on the side of the spine where the vessels are located in close approximation to the vertebrae as is the case with the L_4 and L_5 vertebrae where the vessels are located over the left side of those vertebrae. It is appreciated that any of the securing means 65-65b, described above may be used to lock the screw 60b to the extension arm 392.--

Page 30, first full paragraph:

--The top member 714 has a hole 728 on one end and a hole 730 at its other end through which each of the projection screw members 716 and 717 respectively, may pass. The projection screw members 716 and 717 pass through the holes 728 and 730 to engage the vertebrae V. Each of the holes 728 and 730 has a concentric counter sunk recess 732 for receiving and seating the screw heads 724 and 726 of the projection screw members 716 and 717 so that the screw heads 724 and 726 are flush or below the top surface 20 of the stop member 714 once inserted into the vertebrae V.--

Paragraph bridging pages 30 and 31:

--Adjacent and proximate to each of the holes 728 and 730 are threaded openings 740 and 742, respectively, for receiving locking screws 744 and 746 respectively. Each of the locking screws 744 and 746 have a head portion 750 and a locking thread portion 754 for threadably and lockably engaging the threaded openings 740 and 742. The locking screws 744 and 746 are attached to the top member 714 after the projection screw members 716 and 717 have been inserted into the vertebrae V. At least a part of the head portion 750 and 752 blocks and preferably makes contact with the screw projections 716 and 717 to prevent any unwanted loosening and outward excursion of the screw projections 716 and 717.--.

IN THE CLAIMS:

Please cancel claim 1 without prejudice or disclaimer of its subject matter and add the following new claims:

--54. An apparatus comprising:

an interbody spinal fusion implant for surgical implantation within a disc space between two adjacent vertebral bodies in a segment of a human spine, said implant comprising upper and lower portions for contacting each of the adjacent vertebral bodies when positioned therein, each of said upper and lower portions having at least one opening adapted to communicate with one of the adjacent vertebral bodies, said openings of said upper and lower portions being in communication with one another and adapted for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant, a hollow interior for holding bone growth promoting material, said hollow interior being in communication with at least one opening in each of said upper

and lower portions, said implant having an insertion end for entry into the spine and a trailing end; and

bone morphogenetic protein for promoting bone growth contained within said hollow interior.

55. The apparatus of claim 54, wherein at least a portion of said upper and lower portions are arcuate along at least a portion of their length.

56. The apparatus of claim 54, wherein said upper and lower portions further comprise a protrusion for engaging the adjacent vertebral bodies.

57. The apparatus of claim 56, wherein said protrusion is a thread.

58. The apparatus of claim 54, wherein at least one of said insertion and trailing ends is open for loading bone growth promoting material into said hollow interior.

59. The apparatus of claim 58, further comprising an end cap for closing said open end.

60. The apparatus of claim 54, wherein said hollow interior is a chamber and the bone growth promoting material includes a bone graft.

61. The apparatus of claim 54, wherein said implant is configured for implantation across the disc space in the thoracolumbar region of the human spine.

62. The apparatus of claim 54, wherein said spinal implant includes an artificial material other than bone.

63. The apparatus of claim 54, wherein said implant is made of an artificial material that is stronger than bone.

64. The apparatus of claim 54, wherein said implant is made of an artificial material that is harder than bone.

65. The apparatus of claim 54, wherein said implant comprises harvested bone.

66. The apparatus of claim 54, wherein said implant is in combination with bone growth promoting material.

67. The apparatus of claim 66, wherein said bone growth promoting material is selected from one of hydroxyapatite and genes coding for the production of bone.

68. The apparatus of claim 54, wherein said implant is treated with a bone growth promoting substance.

69. The apparatus of claim 54, wherein said implant is a source of osteogenesis.

70. The apparatus of claim 54, wherein said implant is at least in part bioabsorbable.

71. The apparatus of claim 54, wherein said implant comprises metal.

72. The apparatus of claim 54, wherein said implant comprises a plastic material.

73. The apparatus of claim 54, wherein said implant comprises a ceramic material.

74. The apparatus of claim 54, wherein said implant is formed of a porous material.

75. The apparatus of claim 54, wherein said implant is formed of a material that intrinsically participates in the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

76. The apparatus of claim 54, wherein said at least one opening is adapted to retain fusion-promoting materials

77. The apparatus of claim 54, wherein at least a portion of said implant is treated to promote bone ingrowth between said implant and said adjacent vertebral bodies.

78. The apparatus of claim 54, wherein said implant is in combination with harvested bone.--.

REMARKS

New claims 54-78 directed to spinal implants containing bone morphogentic protein for promoting bone growth have been added to the Application. Support for this amendment is found in the Application on page 13, line 33 through page 14, line 10 and Figures 12, 32, and 33. No new matter has been added.

Applicant respectfully requests consideration and examination of these claims with this application and a timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for in the papers accompanying this response, such an extension is requested and the fee should also be charged to our Deposit Account.

Should the Examiner have any further questions, please contact the undersigned directly.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: March 15, 2002

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CHANGES TO THE TITLE

~~--APPARATUS, INSTRUMENTATION AND METHOD FOR~~ SPINAL ~~FIXATION~~ IMPLANT CONTAINING BONE MORPHOGENETIC PROTEIN~~--~~.

CHANGES TO THE SPECIFICATION

Please amend the specification as follows:

Paragraph bridging pages 19 and 20:

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rod 70' and prevent the rotation of the staple member 12 about the splined alignment rod 70'. The prevention of rotation about the splined alignment rod 70' is especially important when the Short Method is used to insert the spinal fixation device 10, as no insertion holes 53a and 53b have been drilled in the vertebrae V. The staple 12 can be driven directly into the vertebrae V by the application of a high impaction force to the driving instrument 80 as described above and shown in Figure ~~32~~ 22.--

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center of the bottom surface of the top member 314 is a central member 390 which is similar to the central bar 35 of the preferred embodiment of the spinal fixation device 10 in that the central member 390 interdigitates with the depression ~~44a~~ 44 of the spinal fusion implant 40. However, the central bar 390 also has an extension arm 392 that extends laterally from the top member 314 to span the diameter of an adjacent spinal fusion implant 41. The extension arm 392 interdigitates with the depression 44 of the spinal implant 41. The extension arm 392 has a central aperture ~~374~~ 394 for receiving a screw 60b used to couple the extension arm 392 to the spinal fusion implant 41. In this manner, a single spinal fixation device 310 is capable of ~~interdigitate~~ interdigitating with two adjacent spinal fusion implants 40 and 41 to clock and prevent the rotation and any excursion of the spinal fusion implants 40 and 41. The fixation of two spinal fusion implants 40and 41 is possible while leaving no protruding metal, such as the top member 314, on the side of the spine where the vessels are located in close approximation to the vertebrae as is the case with the L_4 and L_5 vertebrae where the vessels are located over the left side of those vertebrae. It is appreciated that any of the securing means 65-65b, described above may be used to lock the screw 60b to the extension arm 392.--

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724 and 726 of the projection screw members 716 and 717 so that the screw heads 724 and 726 are flush or below the top surface 20 of the stop member 714 once inserted into the vertebrae V.--

Paragraph bridging pages 30 and 31:

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